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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/505,316	04/12/2005	David B Mount, Jr.	1242/50/3 PCT/US	2379

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EXAMINER	
BASI, NIRMAL SINGH	

ART UNIT	PAPER NUMBER
1646	

MAIL DATE	DELIVERY MODE
02/25/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/505,316	MOUNT, JR. ET AL.	
	Examiner	Art Unit	
	NIRMAL S. BASI	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-69* is/are pending in the application.

4a) Of the above claim(s) *6-69* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/20/05, 8/11/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' election with traverse of Group I, claims 1-5, drawn to the isolated SLC26A7 polypeptide of SEQ ID NO: 2, on 11/9/07, is acknowledged. Applicants traverse the election of a single polypeptide. Applicants' traversal is not found persuasive. As stated in the previous Office Action the special technical feature of the invention was found in the prior art, a technical relationship does not exist between the claimed groups, therefore unity of invention is lacking. Further a search of the various polypeptides would not be co-extensive particularly with regard to the literature and especially the sequence search. An examination of the materially different, patentably distinct inventions in a single application would constitute a serious undue burden on the examiner. Claims 6-69 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. The elected claims contain non-elected inventions. Applicant is required to remove the non-elected subject matter from said inventions.

The requirement is still deemed proper and is therefore made FINAL.

2. Arguments filed 11/9/07 have been entered.

3. IDS filed 8/11/06 and 7/20/06 have been considered.

4. Drawings filed 8/4/04 are approved by the examiner.

5. The disclosure is objected to because it contains embedded hyperlinks and/or other form of browser-executable code, for example, see pages 12, 14, 28, 68, 69, 70 etc. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code throughout the specification. See MPEP § 608.01

6. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Claim Rejections - 35 USC § 101 and 35 USC § 112, 1st paragraph

The following is a quotation of 35 U.S.C. 101:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-5 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible, specific and substantial asserted utility or a well established utility.

A specific utility is a utility that is specific to the subject matter claimed, as opposed to a general utility that would be applicable to the broad class of the invention. A "substantial utility" is a utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. A "well established utility" is a utility that is well known, immediately apparent, or implied by the specifications disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art. A well-established utility must also be specific and substantial as well as credible.

Based on the record, there is not a "well established utility" for the claimed invention. Applicant has asserted utilities for the specifically claimed invention of claims 1-5. For example, the specification asserts, the claimed polypeptides can be used for identifying modulators of anion transporters, functionally characterize SLC26 anion transporters as pharmaceutical targets for disease and disorders related to abnormal anion transport activity, use the polypeptide to replace diminished or lost SLC26 function. The contemplated uses of SLC26A7 of SEQ ID NO:2 are screening methods and assays for SLC26A7 activity, treatment of conditions related to aberrant SLC26A7 activity and disease diagnosis. The utilities disclosed in the specification are based on methods of using claimed SLC26A7 of SEQ ID NO:2 as a target for diagnosis and treatment of disorders, for drug-screening methods and to identify agonists and antagonists for diagnosis and treatment.

This invention relates to human SLC26A7 polypeptide of SEQ ID NO:2 (solute carrier 26A7), new members of the SLC family of proteins. SLC26A7 is expressed in a wide variety of tissues and is a chloride transport channel. The SLC family of protein is supported by diverse anion transport properties and has diverse physiological roles, (see specification pages 3 and 4). Further, Mount et al (see IDS, Eur. J. Physiol, 2004, 447:710-721) discloses that the physiological role(s) of individual paralogs of SLC26 is evidently due to variation in both anion specificity and expression pattern. For example, SLC26A2 is involved in chondroyspalsias, SLC26A3 in chloride-losing diarrhea and SCL26A4 in Pendred syndrome and hereditary deafness (see Abstract). Mount further disclose (page 710, column 2), "The SLC26 anion exchangers are a relatively young gene family of highly versatile anion exchangers, with intriguing roles in normal physiology and human pathophysiology. A partial list of physiological processes in which these exchangers play critical roles includes skeletal development, synthesis of thyroid hormone, transepithelial $Na^{+}Cl^{-}$ transport, bicarbonate excretion by the distal nephron, and bicarbonate secretion by the exocrine pancreas. SLC26 exchangers transport an expanding number of monovalent and divalent anions, including sulfate (SO42-), chloride (Cl^{-}), iodide (I^{-}), formate, oxalate, hydroxyl ion (OH^{-}), and bicarbonate ($HCO3^{-}$). Individual paralogs differ significantly in anion specificity, such that SLC26A6 is capable of transporting all of the substrates above . In

contrast, SLC26A4 transports monovalent anions such as Cl^-, I^-, and formate, but not divalent anions such as SO_4^2 and oxalate. Several paralogs function in Cl^-OH^- and Cl^-HCO3^- exchange, with increasingly important roles in transepithelial Na-Cl^- and $HCO3^-$ cotransport. "

The SLC channel family of proteins includes many different members with different ion transporting and physiological functions, activation of which, leads to very different consequences, depending upon the activity of other ion transporting systems in the membrane. The patent application covers a wide spectrum of diseases that are claimed to be treatable by using SLC26A7. Based on prior art and the disclosure of instant application there is no evidence that the claimed invention plays an important role for such a large collection of clinical conditions, at least based on experimental data provided. SLC proteins have different regulatory characteristics, which can not be determined by structural homology alone, especially when a member may belong to a completely new family. SLC26A7 is shown to be related to the afore mentioned SLC ion channels by containing some sequence identity. The family of SLC ion channel proteins all serve to transduce signals by means of ion transport. The different SLC have a diversity in their ion transport functions as well a ligand specificity. Although the various SLC family of ion channel proteins share some sequence homology and domain structure they possess significant differences as disclosed above (e.g. electrophysiological properties, conductance, permeability to various ion and have varied physiological effects). In instant case classifying claimed protein as a SLC protein leaves a lot to the imagination as to its role in the cellular signaling pathway and its physiological function. In essence, further experimentation is required to determine a utility for SLC26A7 of SEQ ID NO:2. Cells are exposed to may extracellular stimuli, yet they respond appropriately only to specific signals, often by means of just a handful of intracellular messengers. There is more to specificity than the controlled expression of signaling proteins. As disclosed above, the expression of various SLC proteins leads to very different consequences. However, no disclosure is provided within the instant specification on what specific function SLC26A7 possesses apart from being possibly able to exchange Cl^-, nor are any disease states disclosed that are directly related to SLC26A7 dysfunction. SLC proteins are known to play different roles in numerous cellular signaling contexts , but it is not known what role SLC26A7 plays in said signaling and what would be the use of activating or inhibiting it functionality, apart from determining SLC26A7 dysfunction and as targets for drug discovery.

The utilities asserted by Applicant are not specific or substantial. Since no specific function of SLC26A7 of instant invention is known, and the ability of SLC26A7 channel to transport ions with no associated function is not considered a well established utility, the hypothesized functions are based entirely on conjecture from homologous polypeptides, the asserted utilities are not specific to instant polypeptide, but rather are based on family attributes. Neither the specification nor the art of record disclose the protein of SEQ ID NO:2 useful to identify drugs that affect said protein and modulate its activity. Similarly, neither

the specification nor the art of record disclose any instances where disorders can be affected by interfering with the activity of SLC26A7. Thus the corresponding asserted utilities are essentially methods of using SLC26A7 of SEQ ID NO:2 polypeptide to identify or treat disease states associated with SLC26A7 dysfunction and as targets for drug discovery. Therefore the asserted utilities are essentially methods of testing for or for potentially treating unspecified, undisclosed diseases or conditions, which does not define a "real world" context of use. Treating or testing for compounds that interact with SLC26A7 polypeptide, which may be implicated in an unspecified, undisclosed disease or condition would require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use. Since neither the specification nor the art of record disclose any activities or properties that would constitute a real world context of use for SLC26A7, further experimentation is necessary to attribute a utility to the claimed nucleic acids and fragments thereof. See Brenner v. Manson, 383 U.S. 519, 535B36, 148 USPQ 689, 696 (1966) (noting that Congress intended that no patent be granted on a chemical compound whose sole utility consists of its potential role as an object of use-testing, and stated, in context of the utility requirement, that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion."). Therefore the reasons given above SLC26A7 OF SEQ ID NO:2 "A of SEQ ID NO:3 lacks utility.

8. Claims 1-5 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. Since neither the specification nor the art of record disclose any activities or properties that would constitute a real world context of use for the protein disclosed in SEQ ID NO:3 and variants thereof.

9. Claims 1-5 are rejected under 35 U.S.C. 1 12, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant ad that the inventors), at the time the application was filed, had possession of the claimed invention. The claims are drawn to an isolated polypeptide comprising an amino acid sequence having at least 95% identity with the amino acid sequence of SEQ ID NO:2, a polypeptide encoded by a nucleic acid molecule having at least about 70% sequence identity to SEQ ID NO:1, SLC26A7 polypeptide encoded by an isolated nucleic acid molecule which hybridizes to a nucleic acid sequence of SFQ ID NO:I or 3 under wash stringency conditions represented by a wash solution having less than about 200 mM salt concentration and a wash temperature of greater than about 45°C, and which encodes a SLC26A7 polypeptide; and an isolated nucleic acid molecule differing by at least one functionally equivalent

codon from the isolated nucleic acid molecule of one of (a), (b), and (c) of claim 3 in nucleic acid sequence due to the degeneracy of the genetic code, and which encodes a SLC26A7 polypeptide encoded by the isolated nucleic acid of one of (a), (b), and (c) of claim 3.

Claims 1-4 do not do not require that the polypeptide possess any particular ion exchange activity, nor are there any particular conserved domains shown to be essential for activity. Thus, the claims are drawn to a genus of polypeptides that is defined only by sequence identity.

To provide evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of compete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a partial structure in the form of a recitation of percent identity. There is not even identification of any particular portion of the structure that must be conserved. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Naming a type of material generically known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. When one is unable to envision the detailed constitution of a complex chemical compound having a particular function, such as a polypeptide, so as to distinguish it from other materials, as well as a method for obtaining it, conception has not been achieved until reduction to practice has occurred, i.e., until after the polypeptide has been isolated. Thus, claiming all polypeptide that achieve a result without defining what means will do so is not in compliance with the description requirement. Rather, it is an attempt to preempt the future before it has arrived. The claims recite a broad arbitrary structural relationship between the claimed polypeptide sequences, either in terms of its amino acid sequence and the single disclosed species of SEQ ID NO:2. The recited structural relationships are arbitrary since neither the specification nor the prior art discloses any definitive relationship between protein function and % identity or homology at either the nucleotide or amino acid level; and the specification does not describe a single species of nucleic acid that encodes a functional protein that is not either 100% identical to the recited nucleotide sequence or that encodes a polypeptide that is not 100% identical to the recited amino acid sequence.

While one of skill in the art can readily envision numerable species of polypeptide sequences that are at least a given % identity to a recited reference amino acid sequence, one cannot envision which of these also contain a polypeptide with an undisclosed ion exchange activity. The fact remains that the actual polypeptide with a particular activity or the actual amino acid sequences of such a protein *cannot* be envisioned any better when the possible choices are narrowed from all possible sequences to all possible sequences with an arbitrary

structural relationship with a known functional sequence. For example, if one skilled in the art were to make a synthetic polypeptide with 90% identity to the reference amino acid sequence, he would be no more able to say whether it encoded a functional polypeptide than if was only 10% identical to the reference polypeptide sequence. Nor would he be able to say whether the sequence existed in nature or contained a specific ion exchange activity. All ion exchange activities are encompassed by the claims. There is no disclosure of how to make a polypeptide, or even an example of a polypeptide having an amino acid sequence having at least 90% identity with the amino acid sequence of SEQ ID NO:2, wherein the amino acid sequence has the chloride transport activity of SLC26A7. Returning back to percent identity (homology), to put the situation in perspective, the number of possible amino acid sequences of 100 amino acids in length is 20^{100} (approx. 10^{130}) and the number of possible nucleotide sequences of 300 nucleotides in length is 4^{300} (approx. 4×10^{180}) . The number of possible nucleotide or amino acid sequences that are of a given %identity relative to a reference sequence, where all differences between the possible sequences and the reference sequence are substitutions, can be calculated by the following formula:

$$N = XL + X^2L(L-1)/2! + X^3L(L-1)(L-2)/3! + \ldots + X^{n-1}L(L-1)(L-2)\ldots(L-(n-2))/(n-1)! + X^nL(L-1)(L-2)\ldots(L-(n-1))/n!$$

where N is the number of possible sequences, X is the number of different residues that can be substituted for a residue in the reference sequence, L is the length of the reference sequence, n is the maximum number of residues that can be inserted, deleted or substituted relative to the reference sequence at a given % identity. For a nucleotide sequence, X is 3 (alternate nucleotides); for an amino acid sequence, X is 19 (alternate amino acids).

For a 100 amino acid sequence that is at least 90% identical to a reference sequence of 100 amino acids, the number of possible sequences having 9 amino acid substitutions relative to the reference (the penultimate term of the formula) is approximately 6×10^{23}. Whereas the number of possible sequences having 10 amino acid substitutions relative to the reference (the final term of the formula) is approximately 1.1×10^{26}. So the last term is approximately equal to N, i.e. the preceding terms contribute little to the total. It can also be shown that N can be approximated by the formula $X^nL^n/n!$, where $n<<L$. Using this formula to approximate N in this example gives a value of 1.7×10^{26}. For a 300 nucleotide reference sequence, the number of possible 300 nucleotide sequences that are at least 90% identical to the reference is approximately 1.6×10^{56}.

In the present case, the reference amino acid sequence, SEQ ID NO:2 is 656 amino acids long. Using the approximation formula, the number of possible amino acid sequences and nucleotide sequences that are at least e.g. 90% identical to the reference amino acid sequence, would be a very, very large number. While limiting the scope of potential sequences to those that are at least e.g. 85% identical to a reference greatly reduces the number of potential sequences to test, it does not do so in any meaningful way. Thus, limiting the

claims by the recited structural relationships merely reduces the degree of impossibility of making and testing sequences for those, which encode a functional protein encompassed by the claims. Therefore, inclusion of the structural relationships in the claim does not distinguish the instant fact situation from those reviewed in *Amgen, Fiers,* and *Regents of the Univ. Calif.*

The specification does not provide any information on what amino acid residues are necessary and sufficient for a functional activity. The specification also provides no teachings on what amino acid sequence modifications, e.g. insertions, deletions and substitutions, would be permissible in an active claimed isolated polypeptide that would improve or at least would not interfere with the biological activity or structural features necessary for the biological activity and stability of the protein. Since there are no other examples of proteins that have sufficient structural homology with SEQ ID NO:2 to predict functional activity, it is not possible to even guess at the amino acid residues, which are critical to its structure or function based on sequence conservation. Therefore one cannot predict variant amino acid sequences for a biologically active polypeptide. Rather one must engage in case to case painstaking experimental study to determine active variants. Consequently, excessive trial and error experimentation would have been required to identify the necessary amino acid sequence derivatives encoding a biologically active polypeptide with an amino acid sequence differing from SEQ ID NO:2 as claimed since the amino acid sequence of such polypeptides could not be predicted.

The specification discloses only one putative amino acid sequences, SEQ ID NO:2, for a polypeptide having the necessary properties for the disclosed uses, and provides no guidance on obtaining functional polypeptide variants of SEQ ID NO:2 which would be suitable.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111 , clearly states that applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description" inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the ad to recognize that (he or she) invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.,* 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird,* 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF'S were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only isolated polypeptides comprising the amino acid sequence set forth in SEQ ID NO:2 but not the full breadth of the claims meets the written description provision of 35 U.S.C.112, first paragraph. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1 115).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 2 are indefinite because it is not clear what percent sequence identity is encompassed by "having at least about" so as to allow the metes and bounds of the claim to be determined. Knowing the exact percent identity encompassed by the claims is critical because a difference in a few percent alters the number of species encompassed by the claim by the billions.

Claim 3 is indefinite because it is not clear what is a wash solution "having less than about 200mM salt" and a wash temperature of "greater than about 45°C" so as to allow the metes and bounds of the claim to be determined. The wash stringency condition, the salt concentration and temperature all determine the nucleic acids that will bind to the nucleotide of SEQ ID NO:2. Knowing the exact salt concentration and incubation temperature encompassed by the claims is critical because a slight difference in the parameters alters the scope of the nucleic acids that encompassed by the claims.

Claim 4 is indefinite because it is not clear what function is encompassed by a "functional SLC6A7" so as to allow the metes and bounds of the claim to be determined.

Claim 5 recites the limitation "the functional property" in lines 1 and 2. There is insufficient antecedent basis for this limitation in claim 4, upon which it depends.

Claim Rejections - 35 USC § 102

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an

application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 1-5 rejected under 35 U.S.C. 102(e) as being anticipated by Walke et al(US Patent 6,703,495). Walke discloses a polypeptide (SEQ ID NO:10) that has 89.7% sequence identity to SEQ ID No: of instant application and has 87.9% best local similarity. Walke further discloses a polynucleotide (SEQ ID NO:9) that has 99.9% sequence identity to SEQ ID NO1: of instant application and has 99.9% best local similarity. The polynucleotide of Walke has one nucleotide difference at residue 1454, which is W instead of an A. Therefore the polypeptide encoded by the Walke polynucleotide is at least 95% identical to the polypeptide of SEQ ID NO:2 and absent evidence to the contrary, is inherently a chloride channel. The invention of Walke encompasses the nucleotides presented in the sequence listing of patent 6,703,495, and the expression products of said nucleotides (see column 2, lines 33-59). The disclosure of Walke meets the limitations of claims 1-5 absent evidence to the contrary.

Comparison of SEQ ID NO:2 of instant application with SEQ ID NO:10 of Walke

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RESULT 1
US-09-875-811-10
; Sequence 10, Application US/09875811
; Patent No. 6703495
; GENERAL INFORMATION:
;  APPLICANT: Walke, D. Wade
;  APPLICANT:  Scoville, John
;  TITLE OF INVENTION: No. 6703495el Human Transporter Proteins and
Polynucleotides Encoding the
;  TITLE OF INVENTION:  Same
;  FILE REFERENCE: LEX-0186-USA
;  CURRENT APPLICATION NUMBER: US/09/875,811
;  CURRENT FILING DATE:  2001-06-06
;  PRIOR APPLICATION NUMBER: US 60/210,045
;  PRIOR FILING DATE: 2000-06-07
;  NUMBER OF SEQ ID NOS: 13
;  SOFTWARE: FastSEQ for Windows Version 4.0
; SEQ ID NO 10
```

; LENGTH: 656

; TYPE: PRT

; ORGANISM: homo sapiens

US-09-875-811-10

Query Match 89.7%; Score 2984; DB 2; Length 656;

Best Local Similarity 87.7%; Pred. No. 4.7e-296;

Matches 575; Conservative 44; Mismatches 37; Indels 0; Gaps 0;

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Qy          1 MTGAKRKKRSVLWGKMHTPHREDIKQWCKRRLPILEWAPQYNLKENLLPDTVSGIMLAVQ 60
              |||||||:|:|| |||||  ||| |||:||||||:||| ||||||||||||||||||
Db          1 MTGAKRKKKSMLWSKMHTPQCEDIIQWCRRRLPILDWAPHYNLKENLLPDTVSGIMLAVQ 60

Qy         61 QVAQGLSFAMLSSVHPVFGLYGSLFPAIIYAIFGMGRHVATGTFALTSLISANAVERLVP 120
              || |||:||:|||||||||||||||||||||| ||||||||||||||||||:||
Db         61 QVTQGLAFAVLSSVHPVFGLYGSLFPAIIYAIFGMGHHVATGTFALTSLISANAVERIVP 120

Qy        121 QSSRNLTTQSNSSVLGLSEFELQRIGVAAAVSFLGGVIQLVMFVLQLGSATFLLTEPVIS 180
              |: :|||||||:||||||:||:||| ||||||||||||: ||||||||||::||||||
Db        121 QNMQNLTTQSNTSVLGLSDFEMQRIHVAAAVSFLGGVIQVAMFVLQLGSATFVVTEPVIS 180

Qy        181 AMTTGAATHVVTSQVKYLLGIKMPYISGPLGFFYIYAYVFENIKSVQLEALLLSLLSIIV 240
              |||||||||||||||||:|||||||||||||||||||||||:||||||||||:|
Db        181 AMTTGAATHVVTSQVKYLLGMKMPYISGPLGFFYIYAYVFENIKSVRLEALLLSLLSIVV 240

Qy        241 LVLVKELNEQFKRKIKVVLPVDLVLIIAASFACYCTNMENTYGLEVVGHIPNGIPPPRAP 300
              |||||||||||||||||||||||||||||||||||||||||||||||||| ||| ||||
Db        241 LVLVKELNEQFKRKIKVVLPVDLVLIIAASFACYCTNMENTYGLEVVGHIPQGIPSPRAP 300

Qy        301 PMNILSAVLTEAFGVALVGYVASLALAQGSAKKFKYSVDDNQEFLAHGLSNVIPSFLFCI 360
              ||||||||:|||||||||||||||||||||||||:||||||||||||:: || |||
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Db        301 PMNILSAVITEAFGVALVGYVASLALAQGSAKKFKYSIDDNQEFLAHGLSNIVSSFFFCI 360

Qy        361 PSAAAMGRTAGLYSTGAKTQVACLISCIFVLIVIYAIGPLLYWLPMCVLASIIVVGLKGM 420
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        361 PSAAAMGRTAGLYSTGAKTQVACLISCIFVLIVIYAIGPLLYWLPMCVLASIIVVGLKGM 420

Qy        421 LIQFRDLKKYWNVDKIDWGIWISTYIFTICFAANVGLLFGVICTIAIVLGRFPRAKTLSI 480
              ||||||||||||||||||:|||:||||||||||||||:||||||:|||||| |:||
Db        421 LIQFRDLKKYWNVDKIDWGIWVSTYVFTICFAANVGLLFGVVCTIAIVIGRFPRAMTVSI 480

Qy        481 TDMKEMELKVKTEMHDETSQQIKIISINNPLVFLNAKKFSADLMKIILKESDSNQPLDDV 540
               :||||| ||||||  || ||:||||||||||||||| ||| :| ||:  ||||||:
Db        481 KNMKEMEFKVKTEMDSETLQQVKIISINNPLVFLNAKKFYTDLMNMIQKENACNQPLDDI 540

Qy        541 SKCEQNTLLSSLSNGNCNEEASQPCSSEKCSLVLNCSGLTFFDYTGVSTLVELYLDCKSR 600
              |||||||||:||||||||||||| | :||| |:|:||| |||||:||| |||:|:||| |
Db        541 SKCEQNTLLNSLSNGNCNEEASQSCPNEKCYLILDCSGFTFFDYSGVSMLVEVYMDCKGR 600

Qy        601 SVDVFLANCTASLIKAMTYYGDLDTEKPIFFDSVPAAITIIQSNKNLSKASDHSEV 656
              |||| ||:||||||||||||:||:||||||:|| ||||: | ||||||| ||||||
Db        601 SVDVLLAHCTASLIKAMTYYGNLDSEKPIFFESVSAAISHIHSNKNLSKLSDHSEV 656
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Comparison of SEQ ID NO:1 of instant application and SEQ ID NO:9 of Walke.

RESULT 1

US-09-875-811-9

; Sequence 9, Application US/09875811

; Patent No. 6703495

; GENERAL INFORMATION:

; APPLICANT: Walke, D. Wade

; APPLICANT: Scoville, John

; TITLE OF INVENTION: No. 6703495el Human Transporter Proteins and Polynucleotides Encoding the

; TITLE OF INVENTION: Same

; FILE REFERENCE: LEX-0186-USA

; CURRENT APPLICATION NUMBER: US/09/875,811

; CURRENT FILING DATE: 2001-06-06

; PRIOR APPLICATION NUMBER: US 60/210,045

; PRIOR FILING DATE: 2000-06-07

; NUMBER OF SEQ ID NOS: 13

; SOFTWARE: FastSEQ for Windows Version 4.0

; SEQ ID NO 9

; LENGTH: 1971

; TYPE: DNA

; ORGANISM: homo sapiens

US-09-875-811-9

Query Match 99.9%; Score 1970.6; DB 3; Length 1971;

Best Local Similarity 99.9%; Pred. No. 0;

Matches 1970; Conservative 1; Mismatches 0; Indels 0; Gaps 0;

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Qy          1 ATGACAGGAGCAAAGAGGAAAAAGAAAAGCATGCTTTGGAGCAAGATGCATACCCCCCAG 60
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db          1 ATGACAGGAGCAAAGAGGAAAAAGAAAAGCATGCTTTGGAGCAAGATGCATACCCCCCAG 60

Qy         61 TGTGAAGACATTATACAGTGGTGTAGAAGGCGACTGCCCATTTTGGATTGGGCACCACAT 120
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         61 TGTGAAGACATTATACAGTGGTGTAGAAGGCGACTGCCCATTTTGGATTGGGCACCACAT 120
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Qy        121 TACAATCTGAAAGAAAACTTGCTTCCAGACACTGTGTCTGGGATAATGTTGGCAGTTCAA 180
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        121 TACAATCTGAAAGAAAACTTGCTTCCAGACACTGTGTCTGGGATAATGTTGGCAGTTCAA 180

Qy        181 CAGGTGACCCAAGGATTGGCCTTTGCTGTTCTCTCATCTGTGCACCCAGTGTTTGGTTTA 240
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        181 CAGGTGACCCAAGGATTGGCCTTTGCTGTTCTCTCATCTGTGCACCCAGTGTTTGGTTTA 240

Qy        241 TATGGGTCTCTGTTTCCTGCCATAATTTATGCCATATTTGGAATGGGACATCATGTTGCC 300
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        241 TATGGGTCTCTGTTTCCTGCCATAATTTATGCCATATTTGGAATGGGACATCATGTTGCC 300

Qy        301 ACAGGCACCTTTGCCTTGACATCCTTAATATCAGCCAACGCCGTGGAACGGATTGTCCCT 360
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Db        301 ACAGGCACCTTTGCCTTGACATCCTTAATATCAGCCAACGCCGTGGAACGGATTGTCCCT 360

Qy        361 CAGAACATGCAGAATCTCACCACACAGAGTAACACAAGCGTGCTGGGCTTATCCGACTTT 420
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Qy        481 GCCATGTTTGTGCTGCAACTGGGCAGTGCCACATTTGTGGTCACAGAGCCTGTGATCAGC 540
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Qy        541 GCAATGACAACTGGGGCTGCCACCCATGTGGTGACTTCACAAGTCAAATATCTCTTGGGA 600
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Db        541 GCAATGACAACTGGGGCTGCCACCCATGTGGTGACTTCACAAGTCAAATATCTCTTGGGA 600

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Qy        661 GAAAACATCAAGTCTGTGCGACTGGAAGCATTGCTTTTATCCTTGCTGAGCATTGTGGTC 720
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Db        661 GAAAACATCAAGTCTGTGCGACTGGAAGCATTGCTTTTATCCTTGCTGAGCATTGTGGTC 720

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Db        721 CTTGTTCTTGTTAAAGAGCTGAATGAACAGTTTAAAAGGAAAATTAAAGTTGTTCTTCCT 780

Qy        781 GTAGATTTAGTTTTGATTATTGCTGCATCATTTGCTTGTTATTGCACCAATATGGAAAAC 840
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        781 GTAGATTTAGTTTTGATTATTGCTGCATCATTTGCTTGTTATTGCACCAATATGGAAAAC 840

Qy        841 ACATATGGATTAGAAGTAGTTGGTCATATTCCACAAGGAATTCCCTCACCTAGAGCTCCC 900
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        841 ACATATGGATTAGAAGTAGTTGGTCATATTCCACAAGGAATTCCCTCACCTAGAGCTCCC 900

Qy        901 CCGATGAACATCCTCTCTGCGGTGATCACTGAAGCTTTCGGAGTGGCACTTGTAGGCTAT 960
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Db        901 CCGATGAACATCCTCTCTGCGGTGATCACTGAAGCTTTCGGAGTGGCACTTGTAGGCTAT 960

Qy        961 GTGGCCTCACTGGCTCTTGCTCAAGGATCTGCCAAAAAATTCAAATATTCAATTGATGAC 1020
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        961 GTGGCCTCACTGGCTCTTGCTCAAGGATCTGCCAAAAAATTCAAATATTCAATTGATGAC 1020

Qy       1021 AACCAGGAATTTTTGGCCCATGGCCTCAGCAATATAGTTTCTTCATTTTTCTTCTGCATA 1080
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Db      1021 AACCAGGAATTTTTGGCCCATGGCCTCAGCAATATAGTTTCTTCATTTTTCTTCTGCATA 1080

Qy      1081 CCAAGTGCTGCTGCCATGGGAAGGACGGCTGGCCTGTACAGCACAGGAGCGAAGACACAG 1140
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Db      1081 CCAAGTGCTGCTGCCATGGGAAGGACGGCTGGCCTGTACAGCACAGGAGCGAAGACACAG 1140

Qy      1141 GTGGCTTGTCTAATATCTTGCATTTTCGTCCTTATAGTCATCTATGCAATAGGACCTTTG 1200
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Db      1141 GTGGCTTGTCTAATATCTTGCATTTTCGTCCTTATAGTCATCTATGCAATAGGACCTTTG 1200

Qy      1201 CTTTACTGGCTGCCCATGTGTGTCCTTGCAAGCATTATTGTTGTGGGACTGAAGGGAATG 1260
                ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      1201 CTTTACTGGCTGCCCATGTGTGTCCTTGCAAGCATTATTGTTGTGGGACTGAAGGGAATG 1260

Qy      1261 CTAATACAGTTCCGAGATTTAAAAAAATATTGGAATGTGGATAAAATCGATTGGGGAATA 1320
                ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      1261 CTAATACAGTTCCGAGATTTAAAAAAATATTGGAATGTGGATAAAATCGATTGGGGAATA 1320

Qy      1321 TGGGTCAGTACATATGTATTTACAATATGCTTTGCTGCCAATGTGGGACTGCTGTTTGGT 1380
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Qy      1381 GTTGTTTGTACCATAGCTATAGTGATAGGACGCTTCCCAAGAGCAATGACTGTAAGTATA 1440
                ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      1381 GTTGTTTGTACCATAGCTATAGTGATAGGACGCTTCCCAAGAGCAATGACTGTAAGTATA 1440

Qy      1441 AAAAATATGAAAGAAATGGAATTTAAAGTGAAGACAGAAATGGACAGTGAAACCCTGCAG 1500
                |||||||||||||:||||||||||||||||||||||||||||||||||||||||||||||||
Db      1441 AAAAATATGAAAGWAATGGAATTTAAAGTGAAGACAGAAATGGACAGTGAAACCCTGCAG 1500
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Qy       1501 CAGGTGAAAATTATCTCAATAAACAACCCGCTTGTTTTCCTGAATGCAAAAAAATTTTAT 1560
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Qy       1561 ACTGATTTAATGAACATGATCCAAAAGGAAAATGCCTGTAATCAGCCACTTGATGATATC 1620
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Db       1621 AGCAAGTGTGAACAAAACACATTGCTTAATTCCCTATCCAATGGCAACTGCAATGAAGAA 1680

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Db       1681 GCTTCACAGTCCTGCCCTAATGAGAAGTGTTATTTAATCCTGGATTGCAGTGGATTTACC 1740

Qy       1741 TTTTTTGACTATTCTGGAGTCTCCATGCTTGTTGAGGTTTACATGGACTGTAAAGGCAGG 1800
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Db       1741 TTTTTTGACTATTCTGGAGTCTCCATGCTTGTTGAGGTTTACATGGACTGTAAAGGCAGG 1800

Qy       1801 AGTGTGGATGTATTGTTAGCCCATTGTACAGCTTCCTTGATAAAAGCAATGACGTATTAT 1860
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Db       1921 ATCCATTCAAATAAGAATTTGAGCAAACTCAGTGACCACAGTGAAGTCTGA 1971
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Advisory

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NIRMAL S. BASI whose telephone number is (571)272-0868. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Nirmal S. Basi/
Examiner, Art Unit 1646

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